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**UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW JERSEY**

DERMA SCIENCES, INC., COMVITA NEW
ZEALAND LTD., and APIMED MEDICAL
HONEY LTD.

Plaintiffs,

v.

MANUKAMED LTD., MANUKA MEDICAL
LTD., MEDLINE INDUSTRIES, INC., and
LINKS MEDICAL PRODUCTS, INC.

Defendants.

Filed Electronically

CIVIL ACTION NO.
3:12-CV-03388-JAP-LHG

**PLAINTIFFS' BRIEF IN OPPOSITION
TO DEFENDANTS' MOTION TO STAY
PENDING *INTER PARTES* REVIEW OF
THE PATENT-IN-SUIT**

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INTRODUCTION

A stay of this case would indefinitely permit Defendants’ continued sale of infringing products, causing severe market confusion, and thereby undermining Plaintiffs’ leadership position in the \$12,000,000 U.S. market for honey-based wound dressings. The prejudice to Plaintiffs is severe because Defendants are direct competitors and are the only competitors in the honey-based wound dressing market that are not respecting Plaintiffs’ patent rights. And Defendants’ practice of marketing their infringing products as being “Patented” when Defendants have no discernible U.S. patent rights of their own amplifies Plaintiffs’ prejudice from Defendants’ willful infringement.

Moreover, Defendants’ *inter partes* review (“IPR”) petition is unlikely to resolve this case or simplify it. First, the IPR has not been instituted by the United States Patent and Trademark Office (“PTO”)—it is only at the application stage. Second, even if the IPR process is initiated, under the PTO’s previous “reexamination” proceedings, patents were more likely than not to survive reexamination with claims intact. The IPR process is likely to be no different as it involves the same standard of proof. Notably, the particular patent-in-suit here is a “reissue” patent that has been reviewed twice by the PTO already. Furthermore, the grounds asserted by Defendants in the IPR petition are based on a strained construction of the claims and the tenuous use of references unlikely to be found persuasive to the PTO. Thus, the IPR is likely to provide nothing but delay to the resolution of this case.

The stage of this litigation does not weigh in favor of a stay, as the case can be resolved as fast, or faster than, an IPR. For these and the additional reasons discussed below, Plaintiffs respectfully request that the Court deny Defendants’ request for a stay pending the IPR.

BACKGROUND

This action concerns Defendants' unauthorized sales of products that infringe Plaintiffs Derma Sciences, Inc., Apimed Medical Honey Ltd., and Comvita New Zealand Ltd.'s (collectively "Derma") combined rights in United States Patent Number RE42,755 ("the '755 Reissue Patent") titled "Honey-based Wound Dressing." The '755 Reissue Patent was issued to Apimed Medical Honey Ltd. on September 27, 2011 after reissue proceedings in the PTO. Derma Sciences and Comvita New Zealand are exclusive licensees of the '755 Reissue Patent. The '755 Reissue Patent is directed to the use of honey in medical dressings with a gelling compound resulting in a range of possible compositions, including formable or pliable, or both, flexible sheets and pliable putty compositions, which can be used as wound dressings.

The total U.S. market for honey-based wound dressings is approximately \$12,000,000 per year. Wolfenson Decl. ¶ 5. Defendants ManukaMed Ltd. and Manuka Medical Ltd. and Derma are direct competitors in that market, which has five main competitors. Id. ¶ 4. Derma Sciences' sales comprise approximately 90% of the total market. Id. ¶ 5. Defendants have infringed and continue to infringe the claims of the '755 Reissue Patent by making, using, offering to sell, or selling in the United States a variety of wound dressings containing Manuka honey and gelling compounds. And while Defendants have no discernable patents covering their honey-based wound dressings, Defendants claim in their U.S. marketing materials that their products are "Patented." Id. ¶ 6, Ex. 1, p. 4.

Derma filed the Amended Complaint on October 23, 2012. Derma has been in active discussions with the various defendants since the initiation of the case, and a successful settlement was reached with defendants Links and Medline, who have since been dismissed. Derma and the remaining Defendants engaged in active settlement discussions until April 2013. After settlement discussions reached an impasse, the Court issued its Scheduling Order. D.I. 40.

Pursuant to that Order, the parties have exchanged Rule 26(a)(1) Initial Disclosures, and Derma has served its infringement contentions and accompanying document production. Both parties have served requests for production, and Derma has served interrogatories. Under the current Scheduling Order, a disposition of this matter is possible within 18 months. D.I. 40.

Defendants waited until the day before the initial scheduling conference to file an IPR petition with the PTO on April 4, 2013. Derma has until July 10, 2013 to file a preliminary response, and the Patent Trial and Appeal Board (“PTAB”) has until October 10, 2013 to determine whether an IPR should be instituted. To the extent the PTO does not find a reasonable likelihood that Defendants will prevail on at least one of the challenged claims, the examiner “shall refuse the request and shall not order *inter partes* reexamination.” 37 C.F.R. § 1.923. Thus, there may never be an IPR.

LEGAL STANDARD

It is within this Court’s broad discretion to grant or deny Defendants’ request for a stay. *Viskase Corp. v. Am. Nat. Can Co.*, 261 F.3d 1316, 1328 (Fed. Cir. 2001) (“The court is not required to stay judicial resolution in view of the reexaminations.”). A denial of a stay is consistent with the *inter partes* statutory scheme, which contemplates federal court proceedings progressing in tandem with the IPR. *See e.g.*, 37 C.F.R. § 1.985 (requiring notification of concurrent litigation proceedings).

ARGUMENT

I. THIS CASE SHOULD NOT BE STAYED.

A. A Stay Will Prejudice Derma.

Derma will be prejudiced by a stay because Defendants are direct competitors in the honey-based wound dressing market, which features only a few players. Because of the small number of competitors, the impact of conduct such as Defendants’ infringement is magnified,

and every passing day potentially results in another unlawful sale that deprives Derma of revenue and market share, and causes market confusion. This prejudice is sufficient grounds to deny the stay. *E.g.*, *Cordis Corp. v. Abbott Labs.*, No. 07-2265, 2009 U.S. Dist. LEXIS 131892, *5–6 (N.J. 2009) (denying motion to stay because “Abbott’s product directly competes with [Cordis’s] product. . . . If Cordis is required to wait for the PTO to complete its reexamination before enforcing its patents against Abbott, Cordis may be harmed even further.”).

Defendants cite an unpublished District of New Jersey case for the proposition that stays pending reexamination are “freely given” in New Jersey. Mot. at 4–5. Defendants, however, neglect to cite the many cases in which courts, including this Court, routinely deny stays under the same circumstances present here—when the parties are direct competitors. *E.g.*, *Cordis*, U.S. Dist. LEXIS 131892, at*5–6 (N.J. 2009) (denying motion to stay because the parties’ products compete with one another); *Adaptor, Inc. v. Sealing Sys., Inc.*, No. 09-CV-1070, 2010 U.S. Dist. LEXIS 114997, *3 (E.D. Wis. Oct. 21, 2010) (“Given that the reexamination could take two years before litigation even begins, not including any time possibly spent appealing such decision, the potential delay alone is enough to suggest loss of market share and eroded prices if an alleged infringer is allowed to continue its practices in the meantime.”); *Tesco Corp. v. Weatherford Int’l, Inc.*, 599 F. Supp. 2d 848, 852 (S.D. Tex. 2009) (“Because of the limited estoppel effects . . . prejudice from delayed discovery outweigh any mitigating effect these damages might have.”); *Nidec Corp. v. LG Innotek Co., Ltd.*, No. 07cv108, 2009 U.S. Dist. LEXIS 46123, *11–12 (E.D. Tex. April 3, 2009) (“because the parties are direct competitors in the marketplace . . . the Court finds that Plaintiff would suffer undue prejudice resulting from a stay in this case and this factor weighs against granting a stay.”).

The potential prejudice to Derma is compounded by Defendants' practice of falsely claiming in their marketing brochures that their honey-based wound dressings are "Patented." Wolfenson Decl. ¶ 6, Ex. 1, p. 4. Defendants' marketing materials fail to provide any patent or patent application number, and a search of the PTO website revealed no patent held by ManukaMed. Aannestad Decl. ¶ 2, Ex; 1. Defendants' misconduct of simultaneously violating Derma's patent rights while falsely claiming patent rights of their own compounds the likelihood of market confusion.

Defendants' suggestion that there can be no prejudice because Derma has not previously sought a preliminary injunction or expedited discovery fails to acknowledge the full story. Mot. at 6. First, as this Court is well aware, Derma has been engaged in ongoing settlement discussions that resulted in informal exchanges of information and a successful dismissal of defendants Links and Medline. Derma's diligent effort to resolve this matter through settlement demonstrates the urgency of this litigation. Now that settlement negotiations with the remaining Defendants have reached an impasse, this suit should proceed. Second, Derma's decision not to move for a preliminary injunction during settlement negotiations does not mean Derma should lose its right to a *permanent injunction*. One is not a prerequisite of the other. Indeed, as this Court is aware, preliminary injunctions are rare in patent cases. *See Nat'l Steel Car, Ltd. v. Canadian Pacific Ry., Ltd.*, 357 F.3d 1319, 1324 (Fed. Cir. 2004) ("A preliminary injunction is a drastic and extraordinary remedy that is not to be routinely granted") (quoting *Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568 (Fed. Cir. 1993)).

Lastly, Defendants argue, presumptuously, that a stay in the litigation will benefit Derma. Mot. at 6–7. Nothing could be farther from the truth. First, a stay with no restrictions on Defendants' conduct merely prolongs the amount of time Defendants are able to sell their

infringing products with impunity, thereby gaining market share. Second, as discussed more fully below, all claims likely will need to be litigated after the IPR is rejected or resolved. Delaying that process will not save the parties any litigation expense in the long run and indeed risks increasing the expense if this case takes longer to resolve.

B. A Stay Will Not Simplify This Case.

1. The IPR Will Not Resolve This Case.

Defendants' argument that the IPR may result in a dismissal of this case is speculative, at best. Mot. at 11. In the former reexamination proceedings, it was more likely than not that at least one claim would emerge from reexamination. *See* Mallory Decl. Ex. 14 (showing that 58% of former *inter partes* reexamination certificates fail to cancel all patent claims). The new IPR proceedings are expected to be no different as they involve the same standard of proof ("by a preponderance of the evidence") as the former proceedings. 35 U.S.C. § 316(e). Derma has asserted 48 claims against Defendants. The low possibility that every one of those claims will be rejected or changed does not justify a delay of this case. *See e.g., Biax Corp. v. Fujitsu Computer Systems Corp.*, No. 06-CV-364, 2007 U.S. Dist. LEXIS 12973, *5 (E.D. Tex. Feb. 26, 2007) ("The Court agrees that some claims and issues will likely remain after the reexamination has been completed . . . Accordingly, waiting for the completion of the reexamination may only simplify the case to a limited degree. This factor is speculative and does not support a stay."); *see also Life Techs. Corp. v. Illumina, Inc.*, No. 09-706, 2010 U.S. Dist. LEXIS 55623, *10 (D. Del. June 7, 2010) ("when we consider further that these claims involve parties who are in direct competition the potential for irreparable harm caused by a stay of the counterclaim far outweighs the possibility of simplifying some of the claims at issue.")

What is more, a review of the IPR petition shows that the claims of the '755 Reissue Patent are likely to remain intact. The claimed subject matter in the '755 Reissue Patent has

been through two rounds of prosecution to date, so the references cited in the IPR were all either previously considered by the PTO, are cumulative to the references considered in the '755 Reissue Patent, or they are simply irrelevant, as will be briefed to the PTO in opposition to an IPR being initiated.

Because, even if the IPR is granted, the '755 Reissue Patent will likely survive with valid claims, a stay would only delay the many issues that would remain to be litigated, including infringement, willfulness, and damages. Indeed, the range of issues the IPR can address is remarkably narrow, as an IPR proceeding is limited to addressing invalidity questions that arise from prior art or printed publications only. 37 C.F.R. § 1.915 (2013). Moreover, discovery is restricted in IPR proceedings. *Garmin Int'l Inc., v. Cuozzo Speed Techs. LLC*, No. IPR2012-00001 (Pat.Tr. & App.Bd. March 5, 2013) ("Thus, in *inter partes* review, discovery is limited as compared to that available in district court litigation.") As a result, completion of the IPR proceeding would leave most of the issues in this case unresolved and in need of discovery.

Thus, the IPR will offer little, if anything, to reduce the number of issues that will ultimately be litigated in this case. This militates against a stay. *See Robbins v. H.H. Brown Shoe Co., Inc.*, No. 08 CIV. 6885, 2009 U.S. Dist. LEXIS 61910, *5–6 (S.D.N.Y. June 30, 2009) ("there are significant, complex issues, such as infringement, inequitable conduct, and anticipation and obviousness based on prior uses, that will remain after the reexamination. Thus, this factor weighs against granting a stay. ... Given the substantial prejudice to Robbins and the limited potential for simplification of issues through reexamination, a stay is not warranted."); *Wordtech Systems, Inc. v. Microboards Mfg. LLC*, No. 09-04612, 2010 U.S. Dist. LEXIS 47907, *5 (N.D. Cal. Apr. 22, 2010) ("this case involves several counterclaims that are outside the scope of reexamination, and in any event the Court may resolve the issues related to the prior art

without a ruling from the PTO. Therefore, the Court finds that the potential simplification of issues does not weigh in favor of a stay.”).

2. It Is Unlikely That A Stay Will Narrow The Issues.

Defendants have not shown that this case will be simplified by a stay. Defendants first argue that the PTO may invalidate at least some of the claims of the '755 Reissue Patent. Mot. 7–9. In support of that argument, Defendants merely stress that there is no presumption of validity in the IPR proceedings and point to reexamination statistics. This is not enough to show that a stay will simplify the case. *Roy-G-Biv Corp. v. Fanuc Ltd.*, No. 07-CV-418, 2009 U.S. Dist. LEXIS 69004, *8 (E.D. Tex. Apr. 14, 2009) (“To convince this Court that a stay will actually simplify a case, the requesting party must do more than merely proffer oft-cited reexamination statistics and generic judicial efficiency arguments.”) Moreover, Defendants ignore the fact that the '755 Reissue Patent survived the reissue process prior to being asserted in this case. It is well settled that the burden of proving invalidity at trial is “made heavier” after claims have been reissued and have thus been considered twice by the PTO. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1139 (Fed. Cir. 1985) (“Upon reissue the ‘burden of proving invalidity was made heavier’”) (quoting *Fromson v. Advance Offset Plate*, 755 F.2d 1549, 1555 (Fed. Cir. 1985)). Defendants have failed to give this Court any reason why the PTO would change course on its third go-around, regardless of the standard of review.

Defendants further argue that this Court cannot properly construe the claims of the '755 Reissue Patent without a complete IPR history. Mot. at 9–11. This is not so. Per the Court’s Scheduling Order, opening and responding *Markman* briefs will be filed by November 27, 2013. If necessary, a *Markman* hearing will likely take place in early 2014. Thus, claim construction will likely be completed in this case well before a final decision is reached in the IPR proceedings. *See America Invents Act Roadshow*, United States Patent and Trademark Office,

fill presentation available at http://www.uspto.gov/aia_implementation/roadshow.jsp (excerpt attached as Ex. 2 to Mallory Decl.) (providing for a final decision within 18 months).

In addition, there is no indication that “[t]his Court will save time and resources in allowing the PTO to first review” the ’755 Reissue Patent. Mot. at 11. As explained above, the ’755 Reissue Patent has already been through prosecution twice, addressing the same issues as raised in the IPR. Thus, any discussions with the PTO will be consistent with the prior file histories. Further, because the issues raised by Defendants have already been considered and rejected by the PTO on two occasions, the likelihood that the PTO is going to change course now is low, and there is no reason for this Court to delay its own analysis of the asserted claims.

Thus, the high likelihood that the IPR decision will not simplify this case weighs heavily in favor of denying the stay.

C. The Early Stage of Litigation Does Not Weigh in Favor of a Stay.

Defendants’ argument that a stay is appropriate because this litigation is in its early stages is based on an illogical application of case law. Although courts consider a case in its late stages as an important factor in denying stays, it does not follow that a suit in its early stages weighs in favor of a stay. *Wyeth v. Abbott Labs.*, No. 09-4850, 2011 U.S. Dist. LEXIS 9824, *10 (D.N.J. Feb. 1, 2011) (quoting *Sunbeam Products, Inc. v. Hamilton Beach Brands, Inc.*, No. 09cv791, 2010 U.S. Dist. LEXIS 45654, *3 (E.D. Va. May 10, 2010)). As courts have noted

[a]lthough the advanced nature of a case approaching trial may weigh heavily against granting a stay, the opposite inference--that a suit in the early stages should weigh heavily in favor of a stay--is *not true*.

(*Id.*, emphasis added). If anything, here, the early stage of this litigation weighs heavily against a stay, as it prolongs the prejudice suffered by Derma from Defendants’ unlawful sales and potentially improved market position.

II. IN THE ALTERNATIVE, THE COURT SHOULD WITHHOLD RULING ON THE MOTION UNTIL THE EXAMINER DECIDES WHETHER OR NOT THE *IPR* SHOULD BE INSTITUTED.

An IPR may never actually proceed on the '755 Reissue Patent. The American Invents Act of 2011 imposed a higher threshold showing for instituting an IPR. 35 U.S.C. 324 (a). The purpose of this change was to weed out meritless challenges to valid patents such as Defendants' IPR petition. 157 Cong. Rec. S1041 (daily ed. Mar. 1, 2011) (statement of Senator Jon Kyl) ("Senators Feingold and Coburn and I proposed that the bill impose a higher threshold showing for instituting an inter partes, or post-grant review . . . a higher threshold is necessary to weed out marginal challenges . . . The present bill imposes higher thresholds, requiring a reasonable likelihood of invalidity for inter partes review . . ."). Thus, if the examiner does not find a reasonable likelihood that Defendants will prevail on at least one of the challenged claims, the IPR cannot proceed. 37 C.F.R. § 1.923. Such an outcome is likely here given Defendants' strained arguments and the irrelevant nature of the prior art cited in the IPR petition and because the PTO has twice examined the '755 Reissue Patent.

At a minimum, because the decision to institute the IPR is not due until around October 10, 2013, Derma respectfully requests that the Court withhold its ruling on the motion until the PTAB makes the initial determination on Defendants' IPR petition. At that time, the Court can more fully evaluate the PTO's view of the IPR to make an informed determination of whether that proceeding merits a stay of district court proceedings.

CONCLUSION

For the foregoing reasons, Derma respectfully requests that Defendants' motion to stay this case be denied.

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